DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

July 19, 2006

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Dana Kent Hays, D.O.
Boulder Natural Labs, LLC
P.O. Box 20514
Boulder, CO 80308

Ref: # DEN-06-20

Dear Dr. Hays:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.avaflu.com and has concluded that claims in your labeling cause your product "AvaFlu" to be a drug as defined in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)]. You can find the Act and FDA's regulations through links on FDA's Internet home page: http://www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201 (g)(1)(B) of the Act, 21 U.S.C. 321(g)(1)(B)]. Your web site claims that your product is useful in the prevention and treatment of avian flu and other forms of influenza.

The Internet labeling of your product on your web site bears the following claims:

- Photo of the product label: "AvaFlu * * * Advanced Formula Flu . . ."
- "There is no guessing whether I have a cold or flu virus. AvaFlu helps both as well as a broad range of flu like viruses."
- "Fights Flu and Flu-like Viruses[:] * * * Influenza * * * Parainfluenza. . . ."
- "Weaken Drug Resistant Viruses and Slow Virus Replication with glycoprotein inhibitors."

These claims that your product prevents and treats avian flu and other forms of influenza cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)]. Because your product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act [21 U.S C. 321(p)]. Under section 505 of the Act [21 U.S.C. 355(a)], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). This drug is also misbranded within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] because its labeling is false and misleading in that it suggests that this drug is effective for the prevention and treatment of avian flu and other forms of influenza when, in fact, these claims are not supported by competent and reliable scientific evidence.

This letter is not an all-inclusive review of your website and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to enforcement action without further notice. The Act provides for seizure of illegal products and for injunctions against the manufacturers and distributors of illegal products [21 U.S.C. 332 and 334]. Individuals and businesses that violate the Act may also be subject to criminal prosecution.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,

B. Belinda Collins
District Director